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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,959	06/25/2001	Richard Ian Christopherson	DAVI139.001C1	2583

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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1643	

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10/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/888,959	CHRISTOPHERSON ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *28-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *28-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/10/07 and 4/29/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *IDS 9/4/01 and attachment*.

DETAILED ACTION

Claims 1-27 have been canceled. Claims 28-40 have been added and are under consideration.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 29 specifies the method of claim 28 wherein the solid support comprises at least one immunoglobulin selected from the recited Markush group, including kappa, lambda, Anti-hIg and Anti-Ig. Claims 30-34 embody the method of claim 28 wherein the solid support further contains 39, 41, 42, 44 and 52 immunoglobulins selected from the recited Markush group including kappa, lambda, Anti-hIg and Anti-Ig. Thus, claim 29 minimally requires the immunoglobulins which bind to CD3, 4, 8, 14, 19and 56 and one other immunoglobulin; Claims 30-34 require 39, 41, 42, 44 and 52 immunoglobulins in addition to the six of claim 28 which equals 45, 47, 48, 50 and 58 immunoglobulins, respectively. The originally filed disclosure (page 61) describes an antibody array consisting of CD3, 4, 8, 14, 19 and 56 useful to discern between T cell leukemia and B cell lymphoma. the specification further states that sub-populations of cells can be established by using antibodies against an additional 27 CD antigens (page 61, lines 22-23). The specification provides an antibody array in figure 7a which consists of 48 immunoglobulins plus the six "core" immunoglobulins of claim 28. It is noted that none of the immunoglobulins of figure 7a are "kappa", lambda, anti-hIg or anti-Ig, therefore Figure 7a fails to describe the genus of immunoglobulins of claim 32. The specification provides an antibody array in figure 8a which consists of 54 immunoglobulins plus the six "core" immunoglobulins of

claim 28, equaling 60 immunoglobulins. Figure 8a fails to support any of new claims 29-34 requiring 45, 47, 48 and 58 immunoglobulins, respectively. Table 4 describes a tabulation of 51 antibodies including the six core antibodies, wherein none of said antibodies are specific to kappa, lambda, anti-hIg or Anti-Ig. Tables 5, 6 and 7 describe a tabulation of 49 antibodies, of which six are the "core antibodies" leaving 43 antibodies; Tables 5, 6 and 7 include only the anti-hIg, but not "kappa", "lambda" or Anti-Ig. One of skill in the art would reasonably conclude that the originally filed disclosure fails to support new claims 29-40 due to difference in the number f immunoglobulins and the particular immunoglobulins required, such as immunoglobulins to "kappa", "lambda", anti-hIg and anti-Ig versus mIgG1, mIgG2a, mIgG2b, mIgM within the individual disclosed immunoglobulin arrays.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28, 29, 35-37, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diamond et al (WO95/06909) as evidenced by the ATCC attachment in view of Lanza et al (European Journal of Histochemistry, 1996, Vol. 40 suppl. 1, pp. 7-14, cited in a previous action), Chang (Journal of Immunological Methods, 1983, Vol. 65, pp. 217-233,

reference of the IDS filed April 29, 2003) and Ruiz-Arguelles et al (Cytometry, 1998, vol. 34, pp. 39-42, cited in a previous action)..

Diamond et al teach a method for identifying a leukemia of B-cell lineage, versus T cell lineage vs myeloid cell lineage in a human subject comprising flow cytometric analysis of a biological sample taken from a patient (for example, figures 14 and 15, page 73, lines 15-22, page 74, line 42 and page 49) including immunoglobulins which bind to CD2, 3, 4, 5, 7, 8, 10, 11c, 13, 14 (My4 and Mo2), 16, 19, 20, 22, 25, 33, 34, 41, 45, 56, 57, 61 and 71 and immunoglobulins that bind to kappa, lambda, GPA (glycophorin A), and HLA-DR. Diamond et al teach the specific anti-CD14 antibody Mo2, which is a monoclonal antibody as evidenced by ATCC attachment, thus fulfilling the requirement of claim 37.. Diamond et al teach that it is necessary to further analyze some of the samples for percentage in S phase and cell size (Figure 14, for example) which meets the limitation of claim 40 requiring further biochemical analysis. Diamond et al do not teach a single assay device comprising a solid support having the disclosed immunoglobulins arranged in discreet regions.

Lanza et al disclose a flow cytometric method for identifying a leukemic of a T-cell, B-cell or myeloid cell lineage (page 11, Table IV) using monoclonal antibodies to CD64, CD117, CD13, CD33, CD14, CD15, CD61, CD41 and glycophorin A to identify myeloid leukemia cells; monoclonal antibodies to CD2, 3, 4, 5, 7, 8 to identify T lymphoid leukemia cells; monoclonal antibodies to CD79alpha, CD10, CD19, CD20, CD22, CD24, kappa and lambda to identify B-lymphoid leukemia cells in addition of CD9, CD11b, CD11c, CD25, CD34, 38, CD45RO, CD45RA, CD56, CD71, and HLA-DR.. Lanza et al teach that a problem with flow cytometry is that the operator must choose a threshold for positivity, and that this threshold is subjective leading to false positive or false negative results (page 12, first column, second full paragraph). Lanza et al do not teach the use of an antibody array comprising the antibodies used in the flow cytometric determination.

Ruiz-Arguelles et al teach the flow cytometric immunophenotyping of leukemia cells and specifically teach that the relative intensity of a given antigen can be different from normal and thus classified by dim or bright relative to normal.

Chang teaches binding of cells to matrixes of distinct antibodies coated on solid surfaces. Chang teaches that such a matrix can be used to analyze functionally different cell

subpopulations tat express distinct differentiation antigens (page 222, lines 15-18 under the heading of "Discussion"). Chang suggest that the antibody matrix method can be used to determine the proportion of specific subsets in a mixed population, such as the proportions of B-cells, T cells and monocytes in the mononuclear cell fraction (page 223, lines 2-5). Chang et al teach the evaluation of cell binding to the antibody "dots" by means of microscopic examination (page 219, lines 16-17 under the heading "Binding of cells to small areas of antibody-coated surface"), which fulfills the specific embodiment of claim 26 requiring microscopic analysis. Chang teaches that no fluorescent staining was included (page 219, last sentence under the heading "Evaluation of cell binding") and that it allows for exposure to the sample to all the antibodies at discrete location at the same time and thereby saves reagents and saves cell samples (page 222, first paragraph under "Discussion").

It would have been prima facie obvious at the time the claimed invention was made to use all the monoclonal antibodies of Lanza et al and Diamond et al in an antibody matrix in order to differentiate between T cell, B-cell and myeloid leukemia. One of skill in the art would have been motivated to do so by the teachings of Chang on saving time and cellular samples by exposing the cell sample to all of the antibodies by means of the matrix at the same time. Further one of skill in the art would have been motivated to dilute the sample such that not all of the antibody dots were filled to capacity as indicated by Chang. By doing so it would allow for the relative assessment of cell binding relative to a normal cell sample and thus replace the classification of dim or bright as assess by flow cytometry, taught by Ruiz-Arguelles et al , with the actual number of cells adhering to the dot in comparison to the actual number of cells adhering to the dot using a normal sample. This would allow for a comparison to the normal sample to be made which would reflect actually relative differences between antigen expression in the patient sample and the normal sample which can then be construed as relative differences between the phenotype of T-cell leukemia, B-cell leukemia and myeloid cell leukemia. One would also have been motivate to use the method of Chang because it avoid the requirement for fluorescence markers which is part of flow cytometric analysis and therefore reduces the cost of the analysis.

Claims 28, 29 and 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diamond et al, Lanza et al, Chang and Ruiz-Arguelles et al as applied to claims 28, 29, 35-37, 39 and 40 above, and further in view of Shyjan (U.S. 5,674,739).

Claim 38 embodies the method of claim 29 wherein the immunoglobulins are polyclonal.

Shyjan teaches the use of polyclonal antibodies in instances where the target is mutated (column 25, lines 17-21).

It would have been prima facie obvious at the time the claimed invention was made to use polyclonal antibodies to the targeted antigens taught by Diamond et al and Lanza et al. One of skill in the art would have been motivated to do so in order to insure that the targeted antigen will still bind to the immunoglobulin in instances where the targeted antigen is mutated.

All claims are rejected.

All other rejections and objections as set forth or maintained in the previous Office action are withdrawn in light of applicants amendments.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A. Canella/
Ph.D., Primary Examiner
Art Unit 1643

Product Description

Before submitting an order you will be asked to read and accept the terms and conditions of ATCC's Material Transfer Agreement or, in certain cases, an MTA specified by the depositing institution.

Customers in Europe, Australia, Canada, China, Hong Kong, India, Japan, Korea, Macau, Mexico, New Zealand, Singapore, and Taiwan, R.O.C. must contact a local distributor for pricing information and to place an order for ATCC cultures and products.

Cell Biology

ATCC® Number:	**HB-246™** Order this item	**Price:**	**$330.00**
Designations:	26ic	**Depositors:**	RF Todd
Isotype:	IgG2b; kappa light chain		
Biosafety Level:	1	**Shipped:**	frozen
Medium & Serum:	See Propagation	**Growth Properties:**	suspension
Organism:	*Mus musculus* (B cell); *Mus musculus* (myeloma) (mouse (B cell); mouse (myeloma))	**Morphology:**	lymphoblast
Source:	**Cell type: hybridoma:** B lymphocyte		
Cellular Products:	immunoglobulin; monoclonal antibody; against human CD14		
Permits/Forms:	In addition to the MTA mentioned above, other ATCC and/or regulatory permits may be required for the transfer of this ATCC material. Anyone purchasing ATCC material is ultimately responsible for obtaining the permits. Please click here for information regarding the specific requirements for shipment to your location.		

Related Cell Culture Products

Comments:	Animals were immunized with cultured human peripheral blood monocytes. Spleen cells were fused with NS-1 myeloma cells. The antibody reacts with a nonfunctional domain of human CD14. The binding of 26ic does not inhibit CD14 mediated activities, and is useful for detecting CD14 expression by immunofluorescence and or immunocytochemical methods.
Propagation:	**ATCC complete growth medium:** Modified Dulbecco's medium, 90%; heat-inactivated gamma globulin free horse serum, 10%
Subculturing:	Cultures can be maintained by addition or replacement of fresh medium. Start cultures at 2 X 10 exp5 cells/ml and maintain between 1 X 10 exp5 and 1 X 10 exp6 cells/ml. **Medium renewal:** Every 2 to 3 days
Related Products:	Recommended medium (without the additional supplements or serum described under ATCC Medium): ATCC 46-X

References:	22487: Todd RF , et al. Structural analysis of differentiation antigens Mo1 and Mo2 on human monocytes. Hybridoma 1: 329-337, 1982. PubMed: 6208133 23506: Wright SD , et al. CD14, a receptor for complexes of lipopolysaccharide (LPS) and LPS binding protein. Science 249: 1431-1433, 1990. PubMed: 1698311

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